UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

YAKIMA VALLEY MEMORIAL HOSPITAL, a Washington Nonprofit Corporation, Plaintiff, v. WASHINGTON STATE DEPARTMENT OF HEALTH; MARY C. SELECKY, in her official capacity as Secretary of the Washington State Department of Health, Defendants.	NO. 09-CV-3032-EFS **ORDER GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

I. Introduction

This matter comes before the Court on Defendants the Washington State Department of Health and Mary Selecky's (collectively, "DOH") Motion for Summary Judgment, ECF No. 133. The Court held hearing on DOH's motion on Thursday, June 21, 2012, in Yakima, Washington. ECF No. 315. At the hearing, the Court took DOH's motion under advisement and permitted the parties to file supplemental briefing no later than July 3, 2012, addressing the Ninth Circuit's recent decision in *National Association of Optometrists & Opticians, et al. v. Harris*, No. 10-16233, 2012 WL 2126043 (9th Cir. June 13, 2012). For the reasons discussed below, the Court grants DOH's motion and enters judgment in DOH's favor.

II. Background[1]

Plaintiff Yakima Valley Memorial Hospital ("YVMH") brings this as-applied constitutional challenge in an effort to reform DOH's certificate of need ("CON") regulations relating to a specific set of medical procedures. CON laws are market-regulation devices that require applicants for licenses to perform certain healthcare services to demonstrate that the service is needed in the relevant area before the state health agency grants the applicant a license.

A. Washington's PCI Regulations

Washington law requires a CON for "any new tertiary health service." RCW 70.38.105(4)(f).[2] The CON regulations at issue in this matter restrict the number of hospitals that can perform elective percutaneous coronary interventions ("PCI"), a class of non-surgical treatments for coronary heart disease that includes stenting and balloon angioplasty.

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[1] When considering this motion and creating this Background section, the Court does not weigh the evidence or assess credibility. Instead, the Court takes as true all undisputed facts, and views all evidence and draws all justifiable inferences therefrom in favor of the party opposing the motion. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). However, the Court does not accept as true assertions made by the opposing party if they were flatly contradicted by the record. *See Scott v. Harris*, 550 U.S. 372, 380 (2007). Disputed facts and quotations are set forth with citation to the record, while undisputed facts are not.

[2] Washington's CON law was passed in response to a federal statute that conditioned federal health care funding on states' enactment of CON laws, the National Health Planning and Resource Development Act ("NHPRDA"). Pub. L. No. 93-641, 88 Stat. 2225 § 1523 (1975), *repealed by* Pub. L. No. 99-660, 110 Stat. 3743, 3799 § 701 (1986). For a more detailed discussion of the NHPRDA and the history of Washington's CON law, *see* the Court's Order Granting Defendants' Motion for Judgment on the Pleadings, ECF No. 58.

Elective PCIs, as opposed to emergent PCIs, are performed when the patient is stable and no medical emergency requires immediate action.

Washington law initially only permitted hospitals that held a CON for open heart surgery to perform elective PCI procedures, but in 2007, the state legislature amended the CON law, directing DOH to promulgate elective PCI CON regulations for hospitals that do not otherwise perform on-site cardiac surgery.[3] RCW 70.38.128 (2007). The amendment to the CON law also directs DOH to:

> contract for an independent evidence-based review of the circumstances under which elective [PCI] should be allowed in Washington at hospitals that do not otherwise provide on-site cardiac surgery. The review shall address, at a minimum, factors related to access to care, patient safety, quality outcomes, costs, and the stability of Washington's cardiac care delivery system and of existing cardiac care providers . . . The department shall consider the results of this review, and any associated recommendations, in adopting these rules.

Id. In response, DOH contracted with Health Management Associates (HMA), which issued a forty-one page report in September 2007. *See* Eggen Decl., ECF No. 134-1 at 41-82. The HMA report, which was written by John Raba, M.D., and Terry Conway, M.D., contained the recommendations that "[e]lective PCI should not be performed in hospitals without on-site surgery," and that:

> [a]pproval should only be considered for a program that serves a community or patient population with a fully documented pattern of unmet need and where the establishment of a new elective program would not jeopardize the quality standards of an existing interventional program and if the new program was permitted to participate in a well powered, prospective randomized multiple site study assessing the outcome of

[3] The primary concern regarding whether a hospital has "backup" on-site cardiac surgery capabilities is that, although it is rare, complications requiring emergency heart surgery can sometimes arise during PCI procedures. *See* Raba Decl., ECF No. 134-1 ¶ 9.

> elective PCIs performed in hospitals with an without on-site cardiac surgery.

Id. at 54. HMA's report also recommended that regardless of whether a hospital has on-site cardiac surgery capabilities or not, elective PCI should only be performed at hospitals that had a minimum annual volume of 300 procedures, and an "optimal" annual volume of 400 or more procedures, though the report did recognize that "[p]ublications suggest or recommend minimum volumes ranging from >200, 400, 500 to even 600." *Id.* at 56.

Between November 2007 and March 2008, DOH also met with a PCI stakeholders committee of approximately thirty "committee" members and thirty to forty-five additional "caucus" members. The committee issued its final report to DOH in April 2008, noting that hospitals that performed open heart surgery favored a 400-procedure minimal volume while hospitals that did not favored a 200-procedure minimum volume. In December 2008, DOH adopted final elective PCI regulations for hospitals without on-site cardiac surgery. WAC 246-310-700—755.

B. The PCI Regulations

Under the PCI regulations, DOH may only grant certificates of need for new PCI programs to hospitals that are expected to perform an annual minimum of 300 adult elective PCI procedures by the program's third year of operation. WAC 246-310-720(1). Whether a hospital will perform three hundred PCI procedures per year is estimated using the five-step "need forecasting methodology" set forth in WAC 246-310-745(10). First, one calculates the adult PCI "use rate" for the planning area, which is the number of PCI procedures performed per 1,000 residents over the age of fifteen. Second, one calculates the area's "forecasted use rate" by

multiplying the use rate by the planning area's projected population in five years. Third, one computes the planning area's current capacity from data on PCI procedures contained in the state's Comprehensive Hospital Abstract Reporting System and other DOH surveys. Finally, one simply subtracts the area's current capacity from the forecasted use rate to arrive at the planning area's estimated unmet need for PCI procedures five years later.[4] If the number is greater than 300, DOH will approve a new program, and if the number is lower than 300, DOH will not, a process the regulations somewhat-inaccurately refer to as "rounding down."

C. Legal Action

YVMH filed the Complaint in this matter on March 20, 2009, alleging that the PCI regulations were an unreasonable restraint of trade in violation of the Sherman Act, 15 U.S.C. § 1, and unreasonably discriminated against interstate commerce in violation of the dormant Commerce Clause and 42 U.S.C. § 1983. ECF No. 1. The Complaint prays for relief in the form of a judgment modifying the PCI regulations to 1) lower the minimum volume standard to 200 PCI procedures a year, 2) create a "floor" system wherein a new program would be prohibited only if it would cause an existing provider to fall below the minimum volume level, and 3) and modify the need methodology to permit "rounding up." *Id*. The

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[4] Under the PCI regulations, the planning area's current PCI capacity is assumed to remain constant over the forecast period. WAC 246-310-745(10)("Step 3")(c). As discussed below in Section III.B.ii.b.IV, this assumption inures to the benefit of CON applicants because it ties the measure of capacity to the number of PCIs actually performed, thereby preventing current CON holders from increasing their capacity in order to prevent other providers from entering the market.

Complaint also requests an award of costs and attorney's fees and "such other relief as the Court deems just." *Id.* at 9.

On May 25, 2010, the Court granted DOH's motion for judgment on the pleadings. ECF No. 58. The Court held that the PCI regulations were a unilateral restraint on trade, and thus were not barred by the Sherman Act. *Id.* at 11. The Court also found that YVMH had both constitutional and prudential standing to bring its dormant Commerce Clause claim, but found that Congress expressly authorized any burden that the PCI regulations impose on interstate commerce when it passed the NHPRDA, precluding a dormant Commerce Clause claim as a matter of law. *Id.* at 14. YVMH appealed, and DOH cross-appealed the Court's ruling on the issue of standing.

The Ninth Circuit affirmed in part and reversed in part, upholding the Court's Sherman Act and standing rulings, but reversing the Court's ruling that Congress had authorized the regulations' burden on commerce when it passed the NHPRDA, holding that "[DOH] has failed to show that the NHPRDA, a statute repealed without a savings clause, provides the requisite clear statement of authorization for the 2008 PCI regulations." *Yakima Valley Mem. Hosp. v. Wash. State Dep't of Health*, 654 F.3d 919, 933 (9th Cir. 2011). The Ninth Circuit remanded the matter for further proceedings on YVMH's dormant Commerce Clause claim. *Id.* at 935.

In February 2011, while the Ninth Circuit appeal was pending, YVMH filed an application for a CON to perform elective PCIs. DOH denied the application on December 16, 2011, finding that YVMH had not demonstrated a need for a second elective PCI program in the relevant planning area. *See* ECF No. 134-1 at 115-32. YVMH requested an administrative hearing

to contest the Department's decision, which is scheduled to occur on November 6 through 8, 2012. Under the PCI regulations, YVMH is unlikely to secure a PCI CON until sometime around 2022, when the Yakima Valley market's unmet need will exceed 300 procedures.[5]

DOH now moves for summary judgment on the merits on YVMH's dormant Commerce Clause claim, arguing that YVMH has requested relief which the Court cannot grant, and that YVMH will not be able to succeed on the merits of its claim under the test articulated in *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970). For the reasons discussed below, the Court rejects DOH's remedy argument, but finds that YVMH's dormant Commerce Clause claim fails as a matter of law under *Pike*.

III. YVMH's Motion to Supplement the Record

As a preliminary matter, YVMH moves to supplement its response to DOH's motion, asking the Court to consider the final version of the so-called "CPORT-E Study" it referenced in its initial response. ECF No. 299. Because the Court finds this study relevant and helpful in deciding the issues raised by DOH's motion, it grants YVMH's motion to supplement and will consider the study attached to counsel's declaration, ECF No. 301-1.

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[5] Before the Ninth Circuit, DOH did not contest YVMH's assertion that the market's need will not exceed 300 procedures until 2022. *See Yakima Valley Mem. Hosp.*, 654 F.3d at 924. However, as the Ninth Circuit was addressing the Court's ruling granting DOH judgment on the pleadings, which implicates a different standard than the instant summary judgment motion, the Court does not treat this fact as established and mentions it only for background purposes.

IV. Discussion

A. Summary Judgment Standard

Summary judgment is appropriate if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Once a party has moved for summary judgment, the opposing party must point to specific facts establishing that there is a genuine issue for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986). If the nonmoving party fails to make such a showing for any of the elements essential to its case for which it bears the burden of proof, the trial court should grant the summary judgment motion. *Id.* at 322. "When the moving party has carried its burden of [showing that it is entitled to judgment as a matter of law], its opponent must do more than show that there is some metaphysical doubt as to material facts. In the language of [Rule 56], the nonmoving party must come forward with 'specific facts showing that there is a *genuine issue for trial.*'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986) (internal citation omitted) (emphasis in original).

When considering a motion for summary judgment, the Court does not weigh the evidence or assess credibility; instead, "the evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson,* 477 U.S. at 255. This does not mean that the Court accepts as true assertions made by the non-moving party that are flatly contradicted by the record. *See Scott,* 550 U.S. at 380.

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B. Analysis

DOH raises two arguments in support of its motion for summary judgment. First, DOH argues that YVMH has requested relief which the Court cannot order. In the alternative, DOH argues that YVMH cannot show that the burden imposed on interstate commerce by the PCI regulations "is clearly excessive in relation to the putative local benefits." *Pike*, 397 U.S. at 142. The Court addresses each argument in turn.

i. Relief Requested

DOH first argues that the Court should grant its motion because YVMH has requested a form of relief it cannot grant, namely, the Complaint's request that the PCI regulations be "modified." DOH argues that under the severability doctrine established by the Supreme Court, which directs lower courts to issue narrow rulings when confronted with unconstitutional provisions of state law, it would be improper for the Court to modify the PCI regulations; therefore, the Complaint must be dismissed. YVMH responds that the Court can indeed modify the PCI regulations, and alternatively, that the Court can simply invalidate portions of the PCI regulations under the Complaint's request for "such other relief as the Court deems just."

It is well-established that a court confronted with a partially-unconstitutional statute may not take on the "quintessentially legislative work" of "rewriting state law to conform it to constitutional requirements." *Ayotte v. Planned Parenthood of N. New Eng.*, 546 U.S. 320, 329 (2006) (quoting *Virginia v. Am. Booksellers Ass'n, Inc.*, 484 U.S. 383, 397 (1988)). This rule holds special weight in situations where "line-drawing is inherently complex" and that "may call for a 'far more

serious invasion of the legislative domain' than [courts] ought to undertake." *Id.* at 330 (quoting *United States v. Treasury Emps.*, 513 U.S. 454, 479 n.26 (1995)). As such, "[a]fter finding an application or portion of a statute unconstitutional, [the court] next must ask: Would the legislature have preferred what is left of its statute to no statute at all?" *Id.*

Though the Court would indeed refuse to "modify" the CON regulations in the event YVMH were to succeed on the merits of its claim, the Court denies this aspect of DOH's motion as moot because, for the reasons discussed below, the Court finds that YVMH's claim fails as a matter of law.

ii. Dormant Commerce Clause Claim

YVMH also moves for summary judgment on the merits of DOH's dormant Commerce Clause claim. The Commerce Clause of Article I, § 8 of the United States Constitution empowers Congress to "regulate Commerce . . . among the several States." Art. I, § 8, cl. 3. Although the Commerce Clause's terms do not expressly restrain "the several States," courts have long read a negative implication into the clause, termed the "dormant Commerce Clause," that prohibits states from discriminating against interstate commerce. *See Dep't of Rev. of Ky. v. Davis*, 553 U.S. 328, 337 (2008) (citing *Cooley v. Bd. of Wardens of Port of Phil. ex rel. Soc. for Relief of Distressed Pilots*, 12 How. 299, 318-319 (1852); *Gibbons v. Ogden*, 9 Wheat 1, 209 (1824)). "The modern law of what has come to be called the dormant Commerce Clause is driven by concern about 'economic protectionism - that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state

competitors.'" *Id.* at 337-38 (quoting *New Energy Co. of Ind. v. Limbach*, 486 U.S. 269, 273-74 (1988)).

Under modern Supreme Court jurisprudence, lower courts apply two levels of scrutiny when resolving dormant Commerce Clause challenges to state laws. On one hand, a state law that discriminates against interstate commerce is "virtually *per se* invalid," being upheld only if it "advances a legitimate local purpose that cannot be adequately served by reasonable nondiscriminatory alternatives." *Or. Waste Sys., Inc. v. Dep't of Env. Qual. of Or.*, 511 U.S. 93, 99, 101 (1994). A law discriminates against interstate commerce when it gives "differential treatment [to] in-state and out-of-state economic interests that benefits the former and burdens the latter." *Id.*

"By contrast, nondiscriminatory regulations that have only incidental effects on interstate commerce are valid unless 'the burden imposed on such commerce is clearly excessive in relation to the putative local benefits.'" *Id.* at 99 (citing *Pike*, 397 U.S. at 142). "If a legitimate local purpose is found, then the question becomes one of degree," which "will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities." *Pike*, 397 U.S. at 142. "The Supreme Court has consistently held that a state's power to regulate commerce is at its zenith in areas traditionally of local concern." *Kleenwell Biohazard Waste & Gen. Ecology Consults., Inc.*, 48 F.3d 391, 398 (9th Cir. 1995) (citing *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 350 (1977)). "[R]egulations that touch on safety are those that the Court has been most reluctant to invalidate." *Id.* (citing *Raymond Motor*

Trans., Inc. v. Rice, 434 U.S. 429, 443 (1978)). As such, when evaluating state health and safety regulations, courts "must give deference to the State's choice to protect its citizens in [a certain] way" when evaluating the putative[6] local benefits of the law. *Nat'l Ass'n of Optoms. & Opticians LensCrafters, Inc. v. Brown*, 567 F.3d 521, 527 (9th Cir. 2009).

Here, it is undisputed that the PCI regulations do not give differential treatment to in-state and out-of-state interests, and that the *Pike* test applies. Accordingly, the Court considers in turn the burdens the PCI regulations impose on interstate commerce and the putative local benefits of the regulations.

a. Burdens on Interstate Commerce

YVMH asserts that the PCI regulations burden interstate commerce because if it were able to perform elective PCIs, it would engage in commerce in a number of related ways. Specifically, YVMH asserts that if it were able to perform elective PCI procedures, it would solicit out-of-state patients, hire staff from out of state, and purchase additional medical supplies from out-of-state vendors. DOH contests whether YVMH's inability to engage in commerce in these ways creates a burden on interstate commerce, and notes that YVMH's CON application represented

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[6] The word putative is defined as "[r]eputed; believed; supposed." Black's Law Dictionary 1272 (8th ed. 2004). Justice Stewart's use of this particular adjective in *Pike* further signals that courts are to give deference to the asserted benefits of states' public-safety laws. *See, e.g., Pike*, 397 U.S. at 145 ("Although it is not easy to see why the other growers of Arizona are entitled to benefit at the company's expense from the fact that it produces particular crops, *we may assume that the asserted state interest is a legitimate one*." (emphasis added)).

that YVMH would not incur any capital expenditures or start-up costs, or need to hire any new staff, in order to perform elective PCIs. *See* ECF No. 134-1 at 111-115. YVMH argues that DOH's dispute of whether these areas constitute burdens on interstate commerce creates a genuine issue of material fact that precludes summary judgment.[7]

YVMH relies on the declaration of Dennis Hoover, Pharm.D., the administrative director of YVMH's cardiovascular and orthopedic service line, whose statements the Court takes as true for purposes of the instant motion. Dr. Hoover cites a number of areas in which YVMH's inability to perform elective PCIs inhibits its participation in interstate commerce, including:

- Recruitment of cardiologists, who come largely from out-of-state and are more inclined to practice at a hospital that is authorized to perform lucrative elective PCIs;
- Transactions with out-of-state vendors for the $4,563 in medical supplies YVMH purchases for each PCI procedure (a total burden of $465,300 to $697,950 based on Dr. Hoover's estimation of 100 to 150 new PCI procedures per year);

[7] YVMH also repeatedly argues that the Ninth Circuit "held" the PCI regulations impose a burden on interstate commerce when it recounted YVMH's allegations in support of its standing argument. *See Yakima Valley Mem. Hosp.*, 654 F.3d at 933. As noted above in footnote 5, however, the Ninth Circuit issued its opinion in the context of a Rule 12(c) motion, in which all allegations contained in the non-moving party's pleadings are taken as true, and the Ninth Circuit thus did not explicitly decide *any* factual issues. *See United States v. Lummi Tribe*, 235 F.3d 443, 452 (9th Cir. 2000) (recognizing that for law of the case doctrine to apply, "the issue in question must have been 'decided explicitly or by necessary implication in the previous disposition.'" (quoting *Liberty Mut. Ins. Co. v. EEOC*, 691 F.2d 438, 441 (9th Cir. 1982)). Accordingly, the Court rejects YVMH's "law of the case" argument. *See e.g.*, *United States v. Houser*, 804 F.2d 565, 567-69 (9th Cir. 1986) (holding that law of the case doctrine does not apply to denial of prior motion to dismiss on jurisdictional grounds).

- Treatment of out-of-state patients, though YVMH only performed 10 out-of-state PCIs during the past 4.5 years, and YRCC performed 32 (only *one* of which was elective, *see* ECF No. 134-1 at 155-56);
- Advertising that "extend[s] beyond Washington State"; and
- Health care costs.

Hoover Decl., ECF No. 175.

Even taking all of Dr. Hoover's representations as true, however, these incidental burdens on YVMH's ability to participate in commerce are highly attenuated. The PCI regulations do not treat in-state and out-of-state actors differently, nor are they an even-handed law that incidentally makes it harder for out-of-state actors to do business in the state. Instead, in this as-applied challenge, the PCI regulations simply prevent one *in-state* hospital from expanding its services and in turn buying supplies, hiring staff, and recruiting patients who may come from outside the state. The burdens imposed by the PCI regulations are in this sense twice-removed from the paradigmatic dormant Commerce Clause case in which a state is ostensibly regulating interstate commerce. *Compare C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 391 (1994) (striking down statute because it "allows only the favored [local] operator to process waste that is within the limits of the town") *and Hunt*, 432 U.S. at 349-54 (striking down regulation because it made the cost of doing business greater for out-of-state companies than for in-state companies) *with Exxon Corp. v. Gov. of Md.*, 437 U.S. 117, 126 (1978) (holding regulation to be valid because it "creates no barriers whatsoever against interstate [companies]; it does not prohibit the flow of interstate goods, place added costs upon them, or distinguish between in-state and out-of-sate companies in the retail market"). And unlike

the one Circuit Court case to invalidate a state health-related certificate of need law on dormant Commerce Clause grounds, the PCI regulations do not "excuse[] an almost entirely local class of [entities] from the certificate requirement." *Walgreen Co. v. Rullan*, 405 F.3d 50, 55 (1st Cir. 2005). Rather, they apply equally to all hospitals located within the state, and in this as-applied challenge, they actually favor YRCC, an out-of-state entity, over YVMH, an in-state entity. Finally, on an even more fundamental level, the fact that a total of *thirty* Washington hospitals have elective PCI CONs which permit them to treat out-of-state patients, purchase supplies from out-of-state entities, and hire physicians from out of state demonstrates that the state's CON regime does not substantially burden interstate commerce.

In sum, the burdens the PCI regulations place on interstate commerce are nothing like the "discrimination and the erection of barriers or obstacles to the free flow of commerce" with which the dormant Commerce Clause is concerned, *Di Santo v. Commnw. of Penn.*, 273 U.S. 34, 43-44 (1927) (Stone, J., dissenting); on the record before it, the Court finds that the PCI regulations impose little, if any, burden on interstate commerce, and that whatever slight burden there may be is not constitutionally-significant.

b. Putative Local Benefits

DOH asserts that the PCI regulations promote the state's interest in public safety, arguing that the regulations should receive the special deference courts give to safety-related laws under the *Pike* test. In response, YVMH argues that the PCI regulations do not create any public safety benefit, and makes a number of additional arguments in response,

urging that the PCI regulations do not fulfill other state interests, that the 300-procedure minimum volume standard is arbitrary, and that the need methodology entitles current CON-holders to a "forever franchise" or permanent monopoly. The Court considers each argument in turn.

I. Public Safety

YVMH argues DOH will not be able to show that the PCI regulations' chosen annual minimum volume of 300 procedures is any safer than a 200-procedure annual minimum because there are no studies showing a statistical differences in patient outcomes between 200- and 300-procedure minimums. YVMH also argues that DOH's experts "concede" that 200 would have been an acceptable minimum.

YVMH's argument that a 200-procedure minimum would be acceptable may be correct, but it ignores the relevant inquiry: what are "the putative local benefits" of the PCI regulations? While DOH has not presented a substantial body of evidence regarding the local benefits of the PCI regulations, it did present evidence demonstrating that a 300-procedure minimum is preferable to a 200-procedure minimum, thereby creating a local public safety benefit: The 2011 Guideline for Percutaneous Coronary Intervention prepared by the American College of Cardiology Foundation, the American Heart Association Task Force on Practice Guidelines, and the Society for Cardiovascular Angiography and Interventions (hereinafter "ACCF Guideline") gives a "Class I" recommendation to the performance of elective PCIs "at high-volume centers (>400 procedures) with on-site cardiac surgery," while it gives a "Class IIa" recommendation to elective PCIs "at low-volume centers (200 to 400 PCI procedures per year) with on-site cardiac surgery." ECF No. 183 at 101-02. Class I recommendations

are reserved for procedures that "SHOULD be performed/administered," while Class IIa recommendations are for procedures for which "IT IS REASONABLE to perform." *Id.* at 52 (emphasis in original). It is thus reasonable for the DOH to conclude that if a minimum volume of 400 is "safer" than a range of 200-400, a 300-procedure volume is "safer" than a 200-procedure volume.

YVMH also argues that DOH's position is inconsistent with other instances in which it has accepted Class IIa or even Class IIb recommendations, but again, DOH's internal consistency is inapposite to the Court's narrow inquiry into whether the PCI regulations create a local benefit. The same is true of YVMH's criticism of the HMA Report's recommendation of a 300-procedure annual minimum, ECF No. 134-1 at 56. Instead, the HMA Report and the ACCF Guideline are exactly the type of evidence that concretizes the local benefits of a state public safety regulation and entitles it to judicial deference: "Indeed, if safety justifications are not illusory, the Court will not second-guess legislative judgment about their importance in comparison with related burdens on interstate commerce." *Kassel v. Consol. Freightways Corp. of Del.*, 450 U.S. 662, 670 (1981) (internal quotation omitted).

YVMH's arguments about the propriety of the 300-procedure minimum ultimately go to sophisticated healthcare issues that are beyond the scope of a *Pike* dormant Commerce Clause analysis. DOH has submitted a modicum of evidence showing that the 300-procedure minimum produces local safety benefits, and the Court finds that it "must give deference to the State's choice to protect its citizens in this way." *Nat'l Ass'n of Optoms. & Opticians LensCrafters, Inc.*, 567 F.3d at 527.

II. Other State Interests

YVMH also responds that the PCI regulations fail to promote the other interests the state and federal legislatures have associated with CON laws, namely strengthening price competition, increasing access to health care, decreasing health care costs, and ensuring the stability of Washington's cardiac care system. However, insofar as these goals are expressed in RCW 70.38.015, the general "Declaration of public policy" for the "Health planning and development" chapter of Washington law, or in the NHPRDA, a federal statute that was repealed in 1986, and not in RCW 70.38.128, the RCW section that specifically directs DOH to promulgate regulations for elective PCIs at hospitals without on-site cardiac surgery, the Court ignores them because it would not be appropriate to consider either the state's or the federal government's overarching policy goals when evaluating the putative local benefits of the particular regulations at issue in this case.

Furthermore, just as above, the relevant inquiry here concerns the nature and amount of local benefits the PCI regulations produce, not how well DOH has performed in achieving the goals the legislature assigned to it. There is nothing in *Pike* or its progeny that requires courts to consider whether a regulation creates some local benefits at others' expense, and the Court rejects YVMH's argument that DOH must demonstrate that the PCI regulations also promote price competition, access to health care, or reduce health care costs.

III. "Arbitrariness" of Minimum Volume Standard

YVMH also cites statements made by DOH's experts to argue that the 300-procedure minimum volume standard was chosen "arbitrarily," even

arguing at times that DOH's decision was "arbitrary and capricious." YVMH appears to focus on the Ninth Circuit's statements in *Alaska Airlines, Inc. v. City of Long Beach* that a state law "would violate the commerce clause [] if the particular means chosen to achieve its goals were irrational, arbitrary or unrelated to those goals" and that "[i]n sum, we cannot hold that any of the substantive provisions of the ordinance [at issue] are completely arbitrary or unreasonable." 951 F.2d 977, 985 (9th Cir. 1991). However, DOH presented sufficient evidence demonstrating that the PCI regulations were not chosen arbitrarily, and YVMH has not presented any contradictory evidence to create a truly material factual issue in support of this claim.

The statements by DOH's experts that YVMH cites are taken out of context, as they were made in response to very narrow questioning regarding how the particular number of 300 procedures was chosen; as DOH notes, "the 300 standard, for example, could have been 298 or 301." ECF No. 237 at 12 n.7; *see also* Olsen Dep., ECF No. 176-10 at 70:15-25; Raba Dep., ECF No. 176-6 at 115:14-23; Dean Dep., ECF No. 173-1 at 38:2-14. Furthermore, DOH has presented an abundance of uncontroverted evidence demonstrating that it did not reach the PCI regulations' minimum volume standard arbitrarily: DOH commissioned an independent report on the issue, met with stakeholders on either side of the issue, and ultimately chose a minimum volume standard that was consistent with the report and that was a perfect compromise, mathematically at least, between the recommendations of the two stakeholder factions.

Finally, YVMH's argument that the DOH chose an arbitrarily high minimum PCI volume "because [a 200-procedure standard] threatens the

entrenched incumbent providers of elective PCI procedures in Washington," ECF No. 174 at 27, is belied by the fact that DOH has granted nine of the other elective PCI applications it has received since adopting the PCI regulations - eight of which were located in areas that were already home to an existing provider of elective PCIs. *See* Eggen Decl., ECF No. 134-1 ¶ 8. As such, the Court rejects YVMH's argument that the 300-procedure annual minimum is arbitrary.

IV. Need Forecasting Methodology

Finally, YVMH argues that the PCI regulations' need methodology inappropriately 1) enables existing CON-holders to create a "forever franchise," and 2) illogically "rounds down" the area's forecasted need. Both of these arguments fail.

YVMH argues that the need methodology permits existing elective PCI CON-holders to maintain their monopoly by "ensuring that their current capacity keeps pace with forecasted demand." ECF No. 174 at 36. It is unclear how this argument supports YVMH's dormant Commerce Clause claim because in this as-applied challenge, the existing CON-holder, YRCC, is an out-of-state entity. Furthermore, a careful analysis of the PCI regulations demonstrates that YVMH's argument is only superficially correct. Under the need methodology, both the forecasted unmet need and the current capacity are tied to the number of elective PCIs that are currently performed, and as noted above in note 4, the methodology assumes that the area's capacity will remain constant over the forecast period. The need forecasting methodology also inherently assumes that all unmet need will be served by the CON applicant, when in fact a portion of it would likely be split between the applicant and the

existing CON-holder. What all of this means is that existing CON-holders can *not* manipulate the unmet need value by preemptively expanding their capacity; in an area where the population is growing such that the need for elective PCIs will increase by 100 procedures per year, for instance, a CON application would be granted even if the incumbent CON-holder could increase its capacity by the projected 100 procedures each year. In essence, CON applications are not prejudiced by empty hospital beds or operating rooms that are under construction.

YVMH also argues that the need methodology inappropriately "rounds down" the unmet need. But the regulations' approach is absolutely necessary to give effect to the regulations' annual minimum volume: the 300-procedure minimum volume is just that - a minimum - and any method of forecasting an area's unmet PCI need that would find need based on a lower number would be inappropriate. By way of example, if the forecasted unmet need were to be subject to "rounding up," a de facto 151-procedure minimum volume would result. As such, the Court rejects YVMH's argument that the need methodology is arbitrary or irrational.

c. Recent Ninth Circuit Decision in *National Association of Optometrists & Opticians, et al. v. Harris*

The Ninth Circuit's recent decision in *National Association of Optometrists & Opticians, et al. v. Harris*, No. 10-16233, 2012 WL 2126043 (9th Cir. June 13, 2012) (hereinafter "*NAOO*") is highly instructive, and weighs heavily in DOH's favor. In *NAOO*, national eyewear providers challenged a California law that prohibited licensed opticians from offering prescription eyewear at the same location in which eye examinations are performed. The plaintiffs alleged that this law

violated the dormant commerce clause because 1) it precluded interstate companies from offering "one-stop" eyewear shopping, which is the dominant form of eyewear shopping, and 2) interstate firms would incur great financial loss as a result of the challenged laws. After an initial appeal to the Ninth Circuit, the parties filed cross-motions for summary judgment on the merits of the *Pike* analysis. The district court granted the defendants' motion, and the plaintiffs appealed.

The Ninth Circuit affirmed the district court's grant of summary judgment to the defendants. After substantial discussion of dormant Commerce Clause precedent and the *Pike* test, the Ninth Circuit analyzed both prongs of the *Pike* test, as well as the plaintiffs argument that the district court should have considered whether the state's interests could be served by less-burdensome alternatives. Relying on the Supreme Court's decision in *Exxon Corp. v. Governor of Md.*, 437 U.S. 117 (1978), the Ninth Circuit held that the California law did not impose a constitutionally-significant burden on interstate commerce because the Commerce Clause "does not protect 'the particular structure or methods of operation in a retail market.'" *NAOO*, No. 10-16233, 2012 WL 2126043 at *6 (quoting *Exxon*, 437 U.S. at 127). Even though the Ninth Circuit assumed that the law would shift some profits and market share from out-of-state entities to in-state ones, it found that there was no significant burden on interstate commerce because "the dormant Commerce Clause 'protects the interstate market, not particular interstate firms.'" *Id*. (quoting *Exxon*, 437 U.S. at 127-28). YVMH attempts to distinguish *NAOO* and *Exxon* on the basis that the healthcare market is not a retail market, but it does not identify why this difference would be

material to a *Pike* analysis or why the Commerce Clause would protect the particular structure or methods of operation of non-retail markets. And nothing about the Supreme Court's use of the word "retail" in *Exxon* indicates that it was intended to somehow broaden the ambit of the dormant Commerce Clause. Here, where the challenged regulations actually shift market share and profits from an in-state entity to an *out-of-state* entity, YVMH's market-structure argument holds even less weight than that put forth in *NAOO*, and there is even less of an argument that the PCI regulations burden interstate commerce in a constitutionally-significant manner.

With regard to the local benefits of the law in *NAOO*, the Ninth Circuit clarified that the *Pike* test was not concerned with actual benefits but with "*putative* local benefits," ascribing the phrase the same meaning as discussed above in note 6. *Id.* at 8 (emphasis in original) (quoting *Pike*, 397 U.S. at 142). The court further instructed that when "there is no discrimination and there is no significant burden on interstate commerce, we need not examine the actual or putative benefits of the challenged statutes" because if a regulation "does not impose a significant burden on interstate commerce, it follows that there cannot be a burden on interstate commerce that is 'clearly excessive in relation to the putative local benefits' under *Pike*." *Id.* For this reason, the court did not undertake an analysis of whether the putative benefits of the law were "illusory," ultimately stating that "we express no opinion regarding the value of the putative benefits or the actual benefits of the challenged laws." *Id.* at 9. In situations such as the one at bar, where no constitutionally-significant burden on interstate

commerce has been shown, courts are to give even greater deference to the asserted benefits of a state law or regulation.

Most tellingly, the Ninth Circuit in *NAOO* held that when a challenged law does not discriminate against interstate commerce, courts need not examine whether a local interest "could be promoted as well with a lesser impact on interstate activities." *Id.* (quoting *Pike*, 397 U.S. at 142). Acknowledging that *Pike* included an analysis of alternatives among the factors it listed when outlining the dormant Commerce Clause test for nondiscriminatory laws, the Ninth Circuit noted that in the Supreme Court's recent decision in *Department of Revenue v. Davis*, 553 U.S. 328 (2008), the Court distinguished between discriminatory and nondiscriminatory laws, requiring an examination of alternatives for discriminatory laws, but not for nondiscriminatory ones. *Id.* (citing *Davis*, 553 U.S. at 338-39). "Because the challenged laws do not impose a significant burden on interstate commerce . . . [w]e therefore will not consider any evidence regarding alternative means for the State to achieve its goals." *Id.* at 10. This aspect of the Ninth Circuit's ruling forecloses YVMH's claim as a matter of law, because the bulk of YVMH's proffered evidence is directed at undercutting the propriety of the 300-procedure minimum volume versus a 200-procedure minimum.

d. Conclusion

For the reasons discussed above, the Court finds that YVMH has not demonstrated that genuine, material issues of fact exist with regard to its dormant Commerce Clause claim. And on the record before it, the Court finds that DOH has shown that the burden the PCI regulations impose on interstate commerce is not clearly excessive in relation to their

putative local benefits. While the PCI regulations may incidentally prevent YVMH from participating in the interstate healthcare market, they do not impose a constitutionally-significant burden on interstate commerce. And DOH has presented evidence showing that the PCI regulations offer legitimate public health benefits to the people of Washington, evidence to which the Court defers. "Because the challenged laws are not discriminatory and do not impose a significant burden on interstate commerce, it would be inappropriate for [the Court] to determine the constitutionality of the challenged laws based on our assessment of the benefits of those laws and the State's wisdom in adopting them." *Id.* at 9.

V. Conclusion

For the reasons set forth above, **IT IS HEREBY ORDERED**:

1. YVMH's Motion to Supplement its Response in Opposition to Defendants' Motion for Summary Judgment, **ECF No. 299**, is **GRANTED**.

2. DOH's Motion for Summary Judgment, **ECF No. 133**, is **GRANTED**.

3. **Judgment** shall be **ENTERED with prejudice** in DOH's favor.

4. All hearing and trial dates are **STRICKEN** and all pending motions **DENIED as moot.**

5. This file shall be **CLOSED.**

IT IS SO ORDERED. The District Court Executive is directed to enter this Order and to provide copies to counsel.

DATED this 9th day of July 2012.

S/ Edward F. Shea
EDWARD F. SHEA
Senior United States District Judge

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